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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,241	03/09/2006	Rajendra K. Joshi	08201.0065-00000	9619

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BIOGEN IDEC / FINNEGAN HENDERSON, LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
HUYNH, CARLIC K	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
02/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,241	JOSHI ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Requirement for Restriction/Election submitted on November 9, 2007 has been withdrawn and following Requirement for Restriction/Election is used herein.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or group of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 27-28 and 33-49 are drawn to a method for the treatment of cardiac insufficiency, myocardial infarct and/or angina pectoris comprising administering to a patient in need thereof a fumaric acid derivative.

II. Claims 29-49 are drawn to a method for the treatment of asthma and chronic obstructive pulmonary diseases comprising administering to a patient in need thereof a fumaric acid derivative.

III. Claims 50-58 are drawn to a method of inhibiting bronchial smooth muscle cell proliferation comprising bringing bronchial smooth muscle cells directly or indirectly in contact with a fumaric acid derivative.

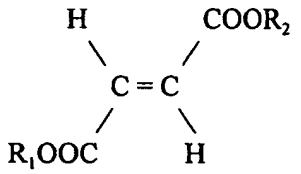
IV. Claims 59-64 are drawn to a method of preparing a fumaric acid derivative.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

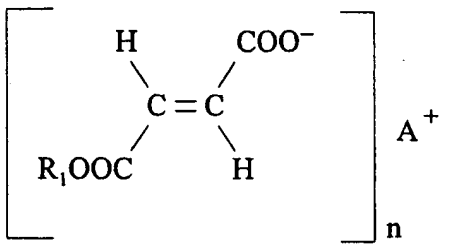
The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step.

The common technical feature in all groups is a fumaric acid derivative of either formula I:

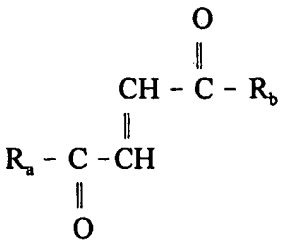


,

II:

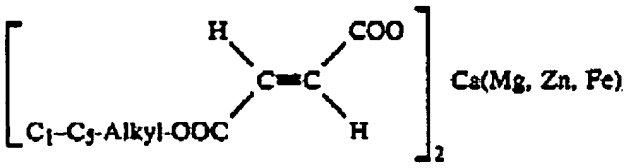


or III:



The element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art.

In this case, Speiser et al. (US 4,959,389 as cited in the IDS) disclose compounds of the formula:



(abstract).

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(1) a fumaric acid derivative of formula I, II, or III;

(2) a cardiac insufficiency;

(3) a form of asthma or chronic pulmonary disease; and

(4) a glucocorticoid.

If Group I is elected, applicant is required, in reply to this action, to elect a single species of (1) a fumaric acid derivative of formula I, II, or III; and (2) a cardiac insufficiency to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group II is elected, applicant is required, in reply to this action, to elect a single species of (1) a fumaric acid derivative of formula I, II, or III; (3) a form of asthma or chronic pulmonary disease; and (4) a glucocorticoid to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group III is elected, applicant is required, in reply to this action, to elect a single species of (1) a fumaric acid derivative of formula I, II, or III to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group IV is elected, applicant is required, in reply to this action, to elect a single species of (1) a fumaric acid derivative of formula I, II, or III; (2) a cardiac insufficiency; (3) a form of asthma or chronic pulmonary disease; and (4) a glucocorticoid to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner: (1) Claims 27-30, 33-37, 41, 49-54, and 57-64 are directed to a fumaric acid derivative of formula I, II, or III; (2) Claims 27-28 and 59-60 are directed to a cardiac insufficiency; (3) Claims 29-30 and 61-62 are directed to a form of asthma or chronic pulmonary disease; and (4) Claims 31-32 and 63-64 are directed to a glucocorticoid.

The following claim(s) are generic: (1) 27-30, 33-37, 41, 49-54, and 57-64; (2) 27-28 and 59-60; (3) 29-30 and 61-62; and (4) 31-32 and 63-64.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: (1) Claims 27-30, 33-37, 41, 49-54, and 57-64 are directed to a fumaric acid derivative of formula I, II, or III, of which each fumaric acid derivative is structurally distinct; (2) Claims 27-28 and 59-60 are directed to a cardiac insufficiency, of which each cardiac insufficiency is operationally distinct; (3) Claims 29-30 and 61-62 are directed to a form of asthma or chronic pulmonary disease, of which each asthma or chronic pulmonary disease is operationally distinct; and (4) Claims 31-32 and 63-64 are directed to a glucocorticoid, of which each glucocorticoid is structurally distinct.

It is noted the fumaric acid derivative must be selected from a **specific** compound of either formula I, II, or III.

The cardiac insufficiency may be selected from, for example, left ventricular insufficiency, myocardial infarct, or angina pectoris.

The form of asthma or chronic pulmonary diseases may be selected from, for example, asthma caused by allergies, asthma caused by infections, asthma caused by analgesics, asthma caused by job conditions, asthma caused by physical effort, mixed forms of asthma, asthma cardiale, or chronic pulmonary disease.

The glucocorticoid may be selected from, for example, dexamethasone, cortisone, hydrocortisone, prednisolone, prednisone, methylprednisolone, flucortolone, triamcinolone beclomethasone, budenoside, flunisonide, fluticasone, or betamethasone.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh